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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/658,121	09/09/2003	Robert W. DeSimone	CGI-0006	9699

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EXAMINER	
WARD, PAUL V	

ART UNIT	PAPER NUMBER
1624	

DATE MAILED: 09/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/658,121	DESIMONE ET AL.	
	Examiner	Art Unit	
	PAUL V. WARD	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-101* is/are pending in the application.

4a) Of the above claim(s) *5-101* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

STATUS: *The previous Office Action (Restriction) dated May 18, 2006, has been vacated and replaced by this Office Action. Applicant is expected to respond to each and every ground of rejection set forth herein below.*

Election/Restrictions

Applicant's election with traverse of Group II in the reply filed on February 28, 2006 is acknowledged. The traversal is on the ground that groups I-IV are inter-related (i.e., part of one and the same invention). Additionally, Applicant contends that there is a linking claim encompassing the scope of all the processes, uses, composition and compounds, and thus, believe that it is inappropriate to restrict since there is a commonality and thus, no burden on the Examiner. This is not found persuasive because Groups I-IV are separate and patentably distinct because there is no patentable co-action among them. For example when X is N or when X is C, a reference anticipating one will not render the other obvious. Hence, Applicant's inventions are distinct and have acquired a separate status in the art due to their recognized divergent subject matter and different classification. Additionally, because each group has different subclasses, it would constitute a burden on the Examiner to search all subclasses. Further, different fields of search would be required in the non-patent literature. Thus, a search of the four groups would impose an undue burden upon the Examiner. Therefore, the restriction for examination purposes as indicated is proper. The requirement is still deemed proper and is therefore made **FINAL**.

Groups I, III and IV are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Applicant reserved the right to file a divisional application to the non-elected subject matter.

Applicant is entitled to have Groups IV rejoined under M.P.E.P. § 821.04, if the claims of Group II are allowable. An amendment, which results in the method claims being commensurate in scope with the allowed claims, will be welcomed.

An action on the merits on Group II on compounds and composition according to claim 1 of Formula I (claims 1-4) is contained herein.

Claim Rejections - 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for other forms, does not reasonably provide enablement for solvates. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The claims are drawn to solvates. But the numerous examples presented all failed to produce a solvate. These cannot be simply willed into existence. As was stated in *Morton International Inc. v. Cardinal Chemical Co.,* 28 USPQ2d 1190, "The

specification purports to teach, with over fifty examples, the preparation of the claimed compounds with the required connectivity. However...there is no evidence that such compounds exist...the examples of the '881 patent to not produce the postulated compounds...there is...no evidence that such compounds even exist." The same circumstance appears to be true here: there is no evidence that solvates of these compounds actually exist; if they did, they would have formed. Hence, applicants must show that solvates can be made, or limit the claims accordingly.

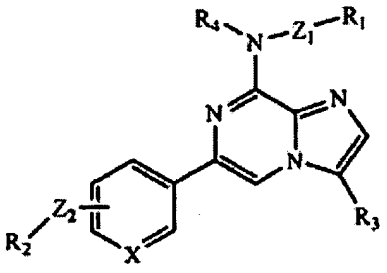
Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Sablayrolles et al. (WO 88/04298).

Applicant teaches imidazopyrazin-8-ylamine compounds having a general formula I:



Formula I

wherein all the variables are as defined in the claim. Additionally, Applicant claims a pharmaceutically acceptable salt comprising the compound of Formula I.

Sablayrolles discloses imidazopyrazin-8-ylamine compounds, which share the same formulaic compounds. (See formula 1, col. 1). The compounds in the said patent has the exact structure, which includes R^4 as H straight or branched chain alkyl, and R^1 as H, straight or branched chain alkyl, Z^1 as CR_7R_8, Z^1 as CR_7R_8, C=0, and X as C, and falls within the range of Applicant's imidazopyrazin-8-ylamine compounds. (See pages 1-3 and Table III pages 18-19). Additionally on page 25, line 15, Sablayrolles teaches pharmaceutical compositions comprising the compounds of Formula I. Since Sablayrolles teaches the exact compounds and compositions, Applicant's claims are anticipated, and thus, rejected under 35 U.S.C. 102(b).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-10, 12 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sablayrolles et al. (WO 88/04298).

Sablayrolles teaches a generic group of imidazopyrazin-8-ylamine derivatives, which embraces Applicants' claimed compounds. (See formula 1, col. 1 and definitions for Y, Z, R^3, R^4). The claims differ from the reference by reciting specific species and a more limited genus than the reference. However, it would have been obvious to one

having ordinary skill in the art at the time of the invention to select any of the species of the genus taught by the reference, including those instantly claimed, because the skilled chemist would have the reasonable expectation that any of the species of the genus would have similar properties, and thus, the same use as taught for the genus as a whole. One of ordinary skill in the art would have been motivated to select the claimed compounds from the genus in the reference since such compounds would have been suggested by the reference as a whole. A prior art disclosed genus of useful compounds is sufficient to render prima facie obvious a species falling within a genus. Thus, Applicant's claims are obvious, and therefore, rejected under 35 U.S.C. 103.

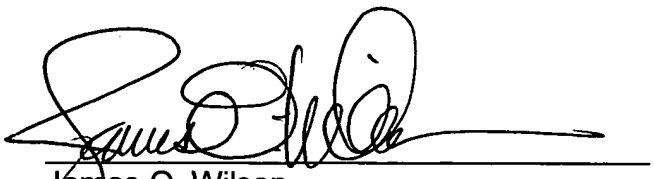
Conclusion

Claims 1-101 are pending. Claims 1-14 are rejected. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAUL V WARD whose telephone number is 571-272-2909. The examiner can normally be reached on M-F 8 am to 4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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